



K060698

MAY 10 2006

## 6.0 510(K) SUMMARY

Pentron Clinical Technologies, LLC.  
68 North Plains Industrial Road  
Wallingford, CT 06492  
Tel: 203-265-7397  
Fax: 203-265-3074  
Contact: Greg Moreau

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Trade Name:	Cement-It All Purpose
Common Name:	Dental resin cement
Classification Name:	Dental Cement, 21CFR 872.3275, EMA

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Cement-It All Purpose product performs the same intended function as its predicate device, MaxCem (reference K041474). Both devices are intended for cementation of porcelain, resin and metal-based inlays, onlays, crowns, bridges and posts. Both devices are not recommended for use on veneer restorations.

The subject device is a self-etch adhesive resin cement in a catalyst/base paste formulation and is a dual cure luting agent. Due to its self-etching and adhering properties, Cement-It All Purpose does not require the use of an etchant, primer or adhesive.

Device composition is approximately 65% filler by weight with filler particle size values less than 2 microns. As with other resin products manufactured by Pentron Clinical Technologies, LLC., the predominant filler for Cement-It All Purpose is a barium borosilicate glass. This filler type provides the subject device with the required strength and radiopacity features.

Product is supplied within automix dual barrel syringes for ease of dispensing directly into the restorative site.

A review for safety and effectiveness was performed and found not to have been affected.

510(k) Submission for Cement-It All Purpose



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 10 2006

Mr. Greg Moreau  
Director, Quality Systems  
Pentron Clinical Technologies, LLC  
68 North Plains Industrial Road  
Wallingford, Connecticut 06492

Re: K060698

Trade/Device Name: Cement-It All Purpose  
Regulation Number: 21 CFR 872.3275(b)  
Regulation Name: Dental Cement  
Regulatory Class: II  
Product Code: EMA  
Dated: April 28, 2006  
Received: May 03, 2006

Dear Mr. Moreau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**5.0 INDICATION FOR USE STATEMENT**

510(k) NUMBER (IF KNOWN): K060698

DEVICE NAME: Cement-It All Purpose

**INDICATION FOR USE:**

Cement-It All Purpose product is intended for cementation of porcelain, resin and metal-based inlays, onlays, crowns, bridges and posts. The material is not recommended for use on veneer restorations.

**(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED.)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use              
(Per 21 CFR 801.109)

OR

Over -The-Counter-Use              
(Optional Format 1-2-96)

510(k) Submission for Cement-It All Purpose

Susan R. [Signature]  
(Official Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
510(k) Number: K060698